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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,576	11/08/1999	CHIH-MING CHEN	300.1003	5401

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/435,576	CHEN ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

--The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

THE REPLY FILED 17 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: _____.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Applicant argues that the combination of references is not proper and there is no motivation to combine. It is argued that the examiner misinterpreted the meaning of Tmax parameter and the values are nowhere to be found on the mean plasma concentration curves of the prior art. Secondly, the applicant argues that there is a marked difference between the bioavailability to humans versus dogs.

Applicant's arguments have been fully considered but they are not persuasive. First, the examiner acknowledges that the prior art does not teach the instant Tmax parameter and rather teaches mean plasma concentration. However, the examiner points out this is a functional property of the product claimed and patentability lies with the product itself. Functional properties are viewed as intended use since applicant is limiting the claim to what happens in-vivo after consumption of the product rather than limiting the product itself. It is pointed out that the primary references (Cheng et al and Alberts) teach the instant drug comprising an alkyl ester of hydroxyl substituted naphthalenes in a controlled release solid dosage for the reduction of serum cholesterol levels. Therefore, the inventive claims are not distinguishable over the prior art. Although applicant has claimed a functional limitation, the applicant has not provided evidence or claimed the feature that makes it different from the prior art. Additionally, it is the examiner's position that one of ordinary skill in the art has the knowledge to formulate the controlled release dosage form with the instant parameters since the prior art provides the guidance to do so. Furthermore, it is quite clear that the process of making controlled release devices and manipulating its parameters are routinely done in the art as seen by the secondary references.

In regards to the human versus dog argument, it is pointed out that Cheng teaches the administration in dog and human models. It is again pointed out that Cheng et al state that "the dog may not be a good model for predicting relative bioavailability of lovastatin or simvastatin." This is by no means is a conclusive statement that the dog data is not instructive with respect to humans since Cheng clearly states "may not." Without data, applicant's arguments do not have substantial weight. Further, it is pointed out that applicant has not recited the critical feature that makes the instant controlled device function differently in humans versus dogs; the applicant merely claims a controlled release dosage form.

Therefore, the rejections are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600